IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

DOMENICK VEGLIA, a minor,	*	
by his parents and natural guardians	*	No. 02-397V
DEBRA VEGLIA and ROB VEGLIA,	*	Special Master Christian J. Moran
	*	
Petitioners,	*	Filed: February 10, 2009
	*	
v.	*	Entitlement, hepatitis B,
	*	meningoencephalitis,
SECRETARY OF HEALTH	*	developmental delay
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

David L. Terzian, Esq., Rawls & McNelis, P.C., Richmond, Virginia, for Petitioner; Althea Walker Davis, Esq., United States Department of Justice, Washington, D.C., for Respondent.

UNPUBLISHED RULING DENYING ONE PORTION OF PETITIONERS' CLAIM[*]

Debra and Rob Veglia claim that the hepatitis B vaccination, received by their son, Domenick, caused Domenick to develop a seizure disorder, and subsequent developmental delays. Pursuant to the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 et seq., the

[*] Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post it on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

All decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, a party has 14 days to identify and to move to delete such information before the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access. 42 U.S.C. § 300aa–12(d)(4); Vaccine Rule 18(b).

Veglias filed a petition seeking compensation for Domenick's injuries. A preponderance of the evidence establishes that the Veglias are not entitled to compensation on this theory. The Veglias have failed to show that Domenick responded to the vaccine in the way predicted by their expert.

Although the Veglias are not entitled to compensation pursuant to a theory that the hepatitis B vaccine caused Domenick's seizures, another avenue of recovery remains possible. Because the Veglias have suggested that Domenick's case might be appropriate for the omnibus autism proceeding, the Clerk's Office is instructed not to treat this ruling as a decision. Instead, the Veglias are offered an opportunity to demonstrate that a transfer to the omnibus autism proceeding is appropriate.

I. Factual History

Six weeks before Domenick was born, his mother was infected with Group B streptococcal cervicitis and was treated with Ampicillin for seven days. Exhibit 4 at 50. His mother received additional antibiotics during delivery. Id. at 59-60, 62. Domenick was born via C-section on May 19, 1999. Exhibit 5 at 29.

His newborn examination was normal. Id. at 5. He received the first dose of the hepatitis B vaccination before discharge from the hospital on May 21, 1999. Id. at 10.

During the first week of June, Domenick's grandmother noticed Domenick's shaking arm. Exhibit 25 (Debra Veglia affidavit) at 1; exhibit 27 (Donna Estrella affidavit) at 1. She pointed this out to Ms. Veglia and suggested that it may be a seizure. Id. Ms. Veglia observed that Domenick's right arm was up and stiff for approximately 20 to 25 seconds. Tr. 13. This

behavior occurred again a few days later. Id. Ms. Veglia asked Domenick's pediatrician , Dr. Burton Schwimmer, who said that it was likely a baby tremor. Exhibit 25 at par. 5.

Domenick saw Dr. Schwimmer on June 17, 1999 for his one-month check-up. At that appointment, he received his second hepatitis B vaccination. Exhibit 13 at 24. Also during that appointment, Domenick had an episode of a leg extension, possibly with tremors. Id.

Domenick was seen again by Dr. Schwimmer on June 30, 1999, this time for complaints of a blank look and eyes rolling back. Id. He was admitted to St. Mary's Hospital that day for further evaluation. Exhibit 6 at 21-73.

At the hospital, Domenick was evaluated for possible seizures by Dr. Laszlo Mate. Exhibit 6 at 29-30. Dr. Mate noted a history of episodes where he would tense up, arch his back, and his eyes would roll back. Id. These episodes lasted anywhere from a few seconds to 20-30 seconds. His mother noticed the first episode at age two weeks, and stated that they had occurred several times since then. Id. A CT scan, MRI and EEG were done and were all normal. Exhibit 6 at 29. In particular, the MRI showed that the "degree of myelination" was "appropriate for [Domenick's] age." On the MRI, Domenick's corpus callosum "appeared normal." Id. at 45-46. The corpus callosum connects the two halves of the brain. Tr. 60. Domenick was discharged on July 1, 1999 with no medication or monitoring. Id. at 28.

According to Ms. Veglia, Domenick had seizures on July 5, 6, 7, 14, and 16. Exhibit 47 at 7-8; tr. at 18. Domenick's next check up with Dr. Schwimmer was on July 16, 1999. Exhibit 13 at 23. Dr. Schwimmer noted that Domenick continued to have "episodes." (Although Dr. Schwimmer did not use the term "seizures," it seems likely that these events were seizures.) He

received the first dose of his diphtheria tetanus ("DT"), haemophilus influenzae ("Hib") and inactivated polio ("IPV") vaccines during this visit. Id.

Domenick was evaluated by Dr. Tatyana Dubrovsky, a pediatric neurologist, on July 26, 1999. Exhibit 23 at 15-16. Dr. Dubrovsky noted this history of "unusual spells" and viewed a videotape of one "episode," where Domenick was "in child seat with flexed arms, eyes deviating up and into the left, somewhat arching and stiff. He has rhythmical tongue-thrusting movements. The whole episode lasted 45 to 50 seconds at a time and at the end, [Domenick] would start crying and arching backwards." Id. at 16.

Dr. Dubrovsky advised the parents to obtain the results of Domenick's metabolic workup taken during his hospital visit. She also advised that she intended to repeat an EEG study while Domenick was asleep and awake. She declined to begin anticonvulsant medication until further information was known. She expressed concern about "the lack of social interaction, maintaining eye contact, absence of social smile, inappropriate visual tracking, evaluation by pediatric ophthalmologist, and the fact that [Domenick] tends to arch backwards." She stated that the episodes indicate a possibility of Sandiffer's syndrome. Id. Sandiffer's syndrome is "intermittent torticollis occurring in children as a symptom of reflux esophagitis or hiatal hernia." Dorland's Illustrated Medical Dictionary (30th Ed. 2003) at 1831.

Domenick had another EEG on July 30, 1999. This result was not normal; the EEG showed evidence of epileptic discharges. Exhibit 22 at 129. Dr. Dubrovsky prescribed phenobarbital as a response to the seizures. Exhibit 23 at 16. By August 26, 1999, it appeared that the phenobarbital was controlling Domenick's seizures. Id. at 17.

Domenick returned to Dr. Schwimmer for his 4-month check-up on September 23, 1999. At this visit, he received the second doses of his DT, Hib, and IPV vaccinations. Exhibit 13 at 21.

By a September 28, 1999 visit with Dr. Dubrovsky, Domenick had developed breakthrough seizures, primarily while falling asleep. Exhibit 23 at 13. In addition to seizures, it was found that Domenick was blind or had limited visual perception and that the "possibility of aggressive CNS degenerative disorder affecting his gray and possibly white matter is very high in the list." Id. His developmental delays were also noted at this visit. Id. at 13. Dr. Dubrovsky increased Domenick's phenobarbitol, recommended aggressive therapies, and stated that she would review the results of the MRI and other tests performed during Domenick's admission to the hospital. Id.

Domenick stayed at Joe DiMaggio Children's Hospital in Hollywood, Florida from September 29, 1999 to October 1, 1999. Exhibit 22 at 137. During this stay, his EEG was abnormal. Id. at 165. Domenick had another MRI of his brain, which was normal. Id. at 155. About six-months later, another pediatric neurologist reviewed the September 29, 1999 MRI and stated that it showed "some global degeneration from [the] initial MRI in July of 1999." Exhibit 9 at 35-36 (report dated Feb. 17, 2000).

After leaving DiMaggio Children's Hospital, Domenick had more seizures. These seizures brought him back to the hospital on October 9, 1999. He stayed until October 13, 1999. Exhibit 22 at 13.

After a series of tests, Dr. Stuart Brown assessed Domenick with an "intractable seizure disorder of generalized and partial types" and developmental delay. Exhibit 22 at 19. There was no clear etiology for Domenick's condition. Id.

Unfortunately, Domenick's condition continued to deteriorate. His seizures increased in both occurrence and length, and involved more of his body. Exhibit 23 at 14. His developmental delay also became more pronounced. By December 1999, Domenick began losing developmental milestones. Exhibit 23 at 19.

On January 13, 2000, Domenick was evaluated by Dr. Byron Lan, Director of Visual Physiology at the Bascom Palmer Eye Institute. Exhibit 17 at 57. Dr. Lam reported that a full field electroretinogram (ERG) was normal but the flash visual evoked potentials (VEP) "showed definite, but irregular response," suggesting reduced central visual pathway function. Id.

Domenick also had a follow up visit with Dr. Dubrovsky on that day. Exhibit 23 at 19. Dr. Dubrovsky noted a decline in head growth and further developmental delay. Id. After ruling out many other potential causes, Dr. Dubrovsky considered Alper's disease as a possible cause of Domenick's condition. Id. Alper's disease is "atrophy of the cerebral gray matter." Dorland's at 54, 1476.

Domenick received his third hepatitis B vaccination on January 28, 2000. Exhibit 13 at 2. He was admitted to the hospital on February 17, 2000 with right pneumonia, intractable seizures, cortical blindness, and developmental delay and regression. Exhibit 9 at 9-11. Domenick had several different tests. A chromosomal test was normal. Id. at 34. An EEG demonstrated "inter-itcal epileptiform activity over both occipital head regions with the type seen in patients with

partial epilepsy." Id. at 38. Dr. Dubrovsky reported that a test for mitochondrial mutations was negative. Exhibit 23 at 24.

An MRI, Domenick's third MRI, showed prominent bifrontal and bitemporal subarachnoid spaces, a decrease in white matter volume, and a thin-appearing corpus callosum. Exhibit 9 at 30. Section III.B, below, discusses this MRI in more detail.

Domenick was discharged in stable condition, and with several medications, on February 20, 2000. Exhibit 9 at 11.

By April of 2001, Dr. Dubrovsky noted that Domenick's condition had slightly improved, in that he regained head control, could sit without support for several minutes, and could roll over. Exhibit 23 at 23-24. At this point, he was experiencing around two seizures each day. Id. at 23. Despite the numerous tests that had been performed, none were able to provide a cause or a diagnosis for Domenick's condition. Dr. Dubrovsky noted that Domenick had received the hepatitis B vaccination "with mercury preparation as a stabilizer" when he was two days old. Id. at 24. She states that "it is possible that his condition is related to exposure to the compound." Id.

Later medical records show that Domenick continues to undergo therapies and support, but do not provide any clarity on a possible cause for his condition.

II. Procedural History

The petition in this case was filed on April 24, 2002. The Veglias filed exhibits 1-10 in July 2002. They filed several additional sets of exhibits from 2003-2005.

On November 17, 2004, the court issued an order to show cause as to why the case should not be dismissed because some doctors diagnosed Schindler's disease, a chromosomal defect.

On January 14, 2005, the Veglias filed additional (pre-existing) medical reports indicating that testing ruled out Schindler's disease. Exhibit 24. Relatively little happened in this case for the remainder of 2005. This case, along with several other cases in which petitioners alleged that the hepatitis B vaccine caused them some injury, was stayed. In February 2006, this case became active again.

Pursuant to a March 29, 2006 order, the Veglias were instructed to file a status report indicating whether they intended to have their case heard before the present special master or to transfer the case to the omnibus autism proceeding before Special Master Hastings. In a status report filed June 19, 2006, the Veglias decided to remain before the present special master to determine if there is a causal relationship between Domenick's receipt of the hepatitis B vaccine and his seizures, developmental delay, and cortical blindness. The Veglias further stated that if the present special master finds no relationship between the hepatitis B vaccination and Domenick's condition, they may choose, at that time, to transfer the case to the omnibus autism proceeding to determine whether, alternatively, the mercury exposure was the cause of his condition. Pet'r Status Rep't, filed June 19, 2006.

Respondent filed his report, pursuant to Vaccine Rule 4, on July 11, 2006. Respondent stated that the existing record failed to show that the Veglias were entitled to compensation. Respondent indicated that the Veglias were required to present a reliable medical opinion stating that the hepatitis B vaccination caused Domenick's seizure disorder. Resp't Rep't, filed July 11, 2006, at 11.

The Veglias filed the report and curriculum vitae of their expert, Dr. Lawrence Steinman, on March 1, 2007. Exhibits 31-32. They also filed several medical articles that Dr. Steinman cited. Exhibits 33-46.

In response to Dr. Steinman, respondent presented the reports and curriculum vitae of two experts, Dr. John McDonald and Dr. Thomas Leist. Exhibits A-B, F-G. These experts also provided literature, which respondent filed as exhibits C-D, H-J.

A hearing was held on December 13, 2007. Ms. Veglia and Dr. Steinman testified for the petitioners. Dr. McDonald and Dr. Leist testified for respondent. After the parties filed post-trial briefs, the case is ready for decision.

III. Analysis

To receive compensation under the Program, the Veglias must prove either: (1) that Domenick suffered a "Table Injury"--*i.e.*, an injury falling within the Vaccine Injury Table – corresponding to the hepatitis B vaccination, or (2) that he suffered an injury that was actually caused by a vaccine. See 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1); Capizzano v. Sec'y of Health and Human Servs., 440 F.3d 1317, 1320 (Fed. Cir. 2006). Here, the Veglias do not claim that Domenick suffered a table injury. Pet'r Post Hearing Br. at 1. Thus, they must prove causation in fact.

A petitioner may not be given an award in the Vaccine Program based solely on the petitioner's claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. 42 U.S.C. § 300aa-13(a)(1). In determining whether a petitioner is entitled to compensation, the special master shall consider all material contained in the record. 42 U.S.C. § 300aa-13(b)(1). This universe necessarily includes "any . . . conclusion,

[or] medical judgment . . . which is contained in the record regarding . . . causation . . . of the petitioner's illness." 42 U.S.C. § 300aa-13(b)(1)(A). Here, the Veglias have offered the opinion of Dr. Steinman. Respondent countered with an opinion from Dr. McDonald and Dr. Leist.

In this case, the evidence includes conflicting opinions from each side's experts. The persuasiveness of the experts must be evaluated and the testimony of one side's expert may rejected when a reasonable basis supports such a rejection. Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993). A decision about the persuasiveness of an expert is virtually not reviewable on appeal. Bradley v. Sec'y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The Federal Circuit stated the elements a petitioner must establish to be entitled to compensation. The petitioner's

> burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Sec'y of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Proof of medical certainty is not required; a preponderance of the evidence suffices. Bunting v. Sec'y of Health and Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

A. Medical Theory

To meet their obligation to present a medical theory, the Veglias rely upon the opinion of Dr. Steinman. Pet'r Post Hearing Br. at 12. Dr. Steinman proposes that the hepatitis B vaccine can cause siezures and developmental delay by a process known as molecular mimicry. A

foundation for molecular mimicry is that some parts of an antigen (here, the hepatitis B vaccine) share a portion of the molecular structure of some parts of the human body (here, myelin basic protein). Exhibit 31 at 4; tr. 45-51.

As a general theory, molecular mimicry has often been advanced by petitioners to explain how a vaccine caused a particular disease or illness. E.g., De Bazan v. Sec'y of Health & Human Servs., 70 Fed. Cl. 687, 695 (2007) (tetanus diphtheria vaccination and myelin basic protein), rev'd on other grounds, 539 F.3d 1347 (Fed. Cir. 2008). More specifically, one special master discussed molecular mimicry as a theory to connect causally the hepatitis B vaccine and multiple sclerosis. Werderitsch v. Sec'y of Health & Human Servs., No. 99-301V, 2006 WL 1672884 * 24 (Fed. Cl. Spec. Mstr. May 26, 2006).

In this case, Dr. Steinman explained the theory of molecular mimicry in some detail. Dr. Steinman stated that if Domenick cross-reacted to the hepatitis B vaccine, then the affected part of his body would be inflamed. Tr. 217-18.

Respondent challenges the reliability of molecular mimicry as a theory to explain how the hepatitis B vaccine can cause seizures and developmental delay. See Resp't Post Hearing Br. at 11-14; see also tr. 148-55 (Dr. Leist). However, determining whether molecular mimicry is a reliable theory is not necessary because even if it were accepted, the Veglias have not established that Domenick responded in the way that molecular mimicry predicts.

B. A Logical Sequence of Cause and Effect Showing That the Vaccination Was the Reason for the Injury

The second aspect of the Veglias's proof is that they present "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen, 418 F.3d at 1278.

The sequence of events requires a demonstration, by a preponderance of the evidence, that what is theoretically possible, as described in prong 1 of the Althen test, actually did happen in this case. See Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1355-56 (Fed. Cir. 2006) (holding that the special master did not err in requiring that petitioners "prove that the vaccine actually caused the alleged symptoms in [their] particular case.") (citation omitted).

Here, Dr. Steinman believes that Domenick suffered menigoencephalitis, meaning that he experienced inflammation in his spinal cord and brain. Tr. 78, 80-81. The inflammation is part of the logical sequence of cause and effect that Dr. Steinman proposes. Tr. 217-19. When pressed on cross-examination, Dr. Steinman conceded, appropriately, that if Domenick did not suffer inflammation, then the vaccine did not cause Domenick's injury. Tr. 223-25. Consequently, the crux of the case is whether Domenick experienced inflammation. The parties' implicit agreement that whether Domenick experienced inflammation is a crucial issue in this case is reflected in the attention they devote to this question in their briefs. See Pet'r Post Hearing Br. at 15-16, 18-20; Resp't Post Hearing Br. at 7-11.

A preponderance of the evidence indicates that Domenick did not experience any inflammation in his spinal cord or brain after the vaccinations. Although Dr. Steinman maintains that the evidence shows inflammation, tr. 225; his opinion is not persuasive.

The usual way to detect inflammation in the spinal cord is to perform a spinal tap. But, when Domenick was at St. Mary's Hospital, the doctors did not perform a spinal tap. Tr. 78-79, tr. 90 (Dr. Steinman), tr. 186 (Dr. McDonald); but see tr. 169-70 (Dr. Leist explaining the presence of protein in the spinal fluid is consistent with inflammation but may have other causes also). The decision not to perform a spinal tap is consistent with the doctor's (unexpressed)

belief that Domenick was not suffering from meningoencephalitis. Tr. 85-86 (Dr. Steinman). Without the results of the spinal tap, evidence of inflammation can still be found elsewhere.

The next likely place to see inflammation in the brain and spinal cord is on an MRI. Domenick underwent a series of MRIs on July 1, 1999. The MRI was used with T1 and T2 weighted images. The MRI was given with and without contrast. Exhibit 6 at 45. An MRI with contrast reveals whether there is a breach in the barrier that separates the circulatory system from the brain. If the MRI reveals such a gap, then the disruption is probably relatively recent because the body will usually heal any damage to the blood-brain barrier. Tr. 140-42 (Dr. Leist); see also tr. 170-71 (Dr. Leist), tr. 181-82 (Dr. McDonald). The purpose of administering an MRI with contrast is to look for inflammation. Tr. 91 (Dr. Steinman).

The MRI showed that the "degree of myelination" was "appropriate for [Domenick's] age." On the MRI, Domenick's corpus callosum "appeared normal." Exhibit 6 at 45-46.

The experts agree that Domenick's first MRI was read as normal. It did not show any signs of inflammation. Tr. 91-93 (Dr. Steinman), tr. 134-35, 139-43 (Dr. Leist), tr. 183-85 (Dr. McDonald).

The Veglias have not offered any persuasive reason to discount the significance of the July 1, 1999 MRI. The Veglias argue that Dr. Steinman testified that there was a "discordance" between Domenick's clinical presentation and the information revealed on the MRI. Pet'r Post Hearing Br. at 16, citing tr. 60-64. However, Dr. Steinman's testimony at pages 60-64 addressed Domenick's situation when he had his third MRI, which was in February 2000. In the passage cited by the Veglias, Dr. Steinman's testimony does not address the first MRI. In a separate portion of the Veglias' brief, they discuss the February 2000 MRI. Pet'r Post Hearing Br. at 19.

But again, testimony and arguments about the significance of the February 2000 MRI say little, if anything, about the July 1999 MRI.

The Veglias also contend that "the process of damage is an insidious one because it occurs as the brain continues to change and mature in the natural course of human development." For this proposition, the Veglias cite Dr. Steinman's testimony at transcript page 64 again and also exhibit 49 (Martha C. Ballesteros, MR Imaging of the Developing Human Brain: Part 2. Postnatal Development, 13 RadioGraphics 611 (1993)) at 613. Pet'r Post Hearing Br. at 16.

The import of this argument is not especially clear. One portion – that the human brain changes and matures – is readily accepted and also is well-supported by exhibit 49. The other portion of the statement from the Veglias' brief – that "the process of damage is an insidious one" is not well-supported. Obviously, some types of damage to the brain can have a sudden and rapid onset – traumatic brain injury caused by a car accident is one example. In this case, Dr. Steinman's testimony about some diseases having an insidious onset was in response to a question about multiple sclerosis and amyotrophic lateral sclerosis. Tr. 64. The Veglias have not explained why the progression of multiple sclerosis constitutes a basis for explaining the onset of meningoencephalitis, the condition Dr. Steinman identified.

The Veglias may be intending to argue that meningoencephalitis sets in so insidiously that not enough time elapsed for an MRI to detect inflammation. See tr. 212 (Dr. Steinman's testimony explaining why focality would not appear on an MRI taken when Domenick is two-months). This argument, if accurate, would minimize the significance of the July 1, 1999 MRI.

However, a preponderance of the evidence established that the MRI would have revealed any inflammation if it existed. First, Dr. McDonald testified that "[i]f there had been an acquired

lesion in those first weeks, that first scan should have shown it." Tr. 227. Dr. McDonald's testimony about the usefulness of MRIs in identifying problems in infants's brains is especially credible because Dr. McDonald regularly reviews MRIs of infants. Tr. 181. Dr. Leist also testified that lesions would appear in the July 1, 1999 MRI. Tr. 133-34, tr. 143 ("the lack of any abnormality at that point in time makes it for me extremely unlikely that this child had a meningoencephalitis or, for that matter, an inflammatory process affecting the central nervous system"). Moreover, the decision of the Domenick's treating doctor to obtain an MRI is, presumably, based upon the expectation that the MRI could reveal something was wrong. If the MRI were valueless, then the treating doctor would probably not order it.

Second, medical articles support a finding that an MRI can reveal inflammation in a child only 42-days old. When testimony at the hearing suggested that the value of MRIs might be a contested issue, the parties were given an opportunity to file medical articles on this point. Order, filed Feb. 5, 2008. The articles support Dr. McDonald's opinion. T2-weighted images, which is a type of MRI that Domenick had, display changes to the myelination of parts of the corpus callosum at birth. Exhibit 50 (James W. Murakami et al., Normal Myelination of the Pediatric Brain Imaged with Fluid-Attenuated Inversion-Recovery (FLAIR) MR Imaging, 20 Am. J. Neuroradiol. 1406 (1999)) at 1408 (Table 2); accord tr. 134 (Dr. Leist's testimony that areas of inflammation would have appeared as T-2 lesions).

Thus, Domenick had, on July 1, 1999, a test that would have revealed inflammation in his brain if he were suffering from inflammation. According to Dr. Steinman, "the optimal times for seeing meningoencephalitis on an image . . . would have been sometime in June of '99." Tr. 81.

But, the result of the MRI scans given the first day of July 1999, indicated that Domenick's brain was not inflamed.

Although the July 1, 1999 MRI is powerful evidence that Domenick did not suffer an inflammation, other evidence in the record supports this finding as well. For example, an infant's fontanelles (the soft part of a newborn's skull) often bulge when the brain is inflamed. Tr. 112 (Dr. Steinman discussing infection with strep B); but see tr. 86 (Dr. Steinman discussing herpes type two encephalitis, which does not present with bulging fontanelles). Dr. Leist expected that if Domenick had meningoencephalitis, as predicted by Dr. Steinman, then his fontanelles would have bulged. Tr. 132-33, tr. 167. Dr. McDonald explained that fontanelles would bulge due to intracranial pressure caused by the inflammation. Tr. 187; see also tr. 208.

However, Domenick's fontanelles were not bulging. Tr. 86, tr. 193. This is secondary evidence to support the finding that Domenick's brain was not inflamed.

Domenick underwent a second MRI on September 29, 1999. This MRI was also normal. It showed that "the degree of myelination is within normal limits." Exhibit 22 at 155 (capitalization changed without notation).

In opining about the case, the experts paid little attention to this September 29, 1999 MRI. For respondent's experts, the second MRI provided another opportunity to observe any inflammation. The fact that the second MRI did not show any inflammation confirmed the important information presented on the first MRI – that Domenick was not suffering inflammation. Tr. 142. The Veglias's expert, Dr. Steinman, emphasized the results of the third MRI. See tr. 93-94, 99.

Domenick had a third MRI on February 18, 2000. This MRI included T1-weighted and T2-weighted sequences but not any contrast. This report is not conclusive. Because Dr. Steinman relies so heavily on the findings from this MRI, the radiologist's report is quoted at length:

> Myelinization appears appropriate for the patient's stated age. However, the overall volume of white matter appears to be somewhat diminished. In addition, the corpus callosum has a somewhat thinned appearance, but appears completely formed.
>
> * * *
>
> IMPRESSION: Prominent bifrontal and bitemporal subarachnoid spaces as described above with differential possibilities including atrophy vs. benign external hydrocephalus.
>
> Slight decrease in overall white matter volume as well as thin appearing corpus callosum.

Exhibit 9 at 30.

The testifying experts differed in the significance that they attribute to this report. Dr. Steinman recognized that "the radiologists, who are trying to make an interpretation, were having a little bit of trouble." Tr. 61. He saw "equivocation." Tr. 62. Dr. Steinman testified that Domenick's clinical condition (having seizures repeatedly and impaired vision) did not match the MRI report in that Domenick was doing much worse than what was reported about the MRI. Tr. 62-63.

Dr. McDonald's opinion was that the radiologist "over-read the film." Tr. 184. According to Dr. McDonald, neurologists debate the expected size of parts of the nervous system, especially the corpus callosum. Thus, to Dr. McDonald, the radiologist's view was "subjective."

The February 2000 MRI actually holds little evidentiary weight for three reasons. The primary reason is that it is the third MRI. The two previous MRIs (one on July 1, 1999, and the other on September 29, 1999) were normal. Exhibit 6 at 45; exhibit 22 at 155. If a hepatitis B vaccination caused any inflammation, the inflammation would appear on an MRI taken within a few weeks of the vaccination. Therefore, the most important MRI for detecting any inflammation caused by the hepatitis B vaccine is the MRI performed on July 1, 1999. Tr. 81 (Dr. Steinman), tr. 133-34, tr. 142-143 (Dr. Leist), tr. 227 (Dr. McDonald). The lapse of time means that the February 2000 MRI is not as useful as the earlier two MRIs.[2]

A secondary reason for giving the February 2000 MRI little weight is that if Domenick were suffering from inflammation in his brain, Dr. McDonald expected to see a focal process. Tr. 183-184. Dr. Leist, too, expected that inflammation would appear in discrete areas of the brain. Tr. 134-135. However, Dr. Steinman stated that focality did not appear on the third MRI because the previous hepatitis B vaccinations caused such extensive brain damage that the process of adding myelin to Domenick's brain was delayed. Tr. 212, tr. 228.

The third reason for giving the February 2000 MRI relatively little weight is the quality of the report interpreting the MRI seems questionable. See 42 U.S.C. § 300aa-13(b) (noting that test results are not binding on special masters). Interestingly, Dr. Steinman and Dr. McDonald expressed concerns about the accuracy of the radiologist's report, but from entirely different perspectives. Dr. Steinman suggested that Domenick's clinical factors should have been

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[2] Conceivably, the Veglias could have alleged that the third dose of the hepatitis B vaccination, which Domenick received on January 28, 2000 (exhibit 13 at 2), significantly aggravated his underlying seizure disorder. However, the Veglias have not presented argued this theory explicitly. Moreover, there appears to be little, if any, evidence to support this theory.

reflected in a report indicating that Domenick's brain was more damaged than the radiologist reported. Tr. 62-63. In contrast, Dr. McDonald stated that the radiologist over-read the film and suggested that the radiologist reported too much damage. Tr. 183-84.

Additional questions about the February 2000 MRI stem from the fourth MRI given to Domenick. He underwent another MRI on October 10, 2000. Again, the radiologist reported that "myelination is normal." But, the "corpus callosum is intact but is somewhat thinner than expected for the patient's chronological age." Exhibit 23 at 25.

Dr. Leist explained why Domenick's corpus callosum was thinner than normal. According to him, it was thinner because Domenick's brain was so impaired that the corpus callosum was not performing its normal function of transmitting axons from one hemisphere of the brain to the other. Tr. 143-44. Dr. Steinman agreed that the corpus callosum could thin due to lack of use. Tr. 220.

In sum, the evidence relied upon by Dr. Steinman to show that Domenick had inflammation in his brain is not persuasive. The more persuasive evidence establishes that Domenick did not have inflammation in his brain. Because inflammation is an essential step in the theory proposed by Dr. Steinman, the Veglias have failed to establish "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen, 418 F.3d at 1278. Therefore, they are not entitled to compensation pursuant to a theory that the hepatitis B vaccine – as opposed to any mercury contained in the vaccine – caused the seizures.

C. Temporal Relationship

Given the determination that the Veglias have failed to present "a logical sequence of cause and effect," consideration of the third prong from Althen is not necessary. See Capizzano, 440 F.3d at 1327 (stating that "[t]he second prong of the Althen III test is not without meaning").

IV. Petitioners' Motion To Strike Evidence

During the hearing, the Veglias made an oral motion to strike the testimony of Dr. Leist in which Dr. Leist proposed that a genetic deformity or metabolic problem caused Domenick's problems and another oral motion to strike similar testimony from Dr. McDonald. Tr. 174-75, tr. 211. The Veglias repeated this argument in writing. Pet'r Post Hearing Br. at 22-23. The basis for the Veglias' motion is that although both Dr. Leist and Dr. McDonald believed that a genetic deformity or metabolic problem caused Domenick's developmental delay, neither Dr. Leist nor Dr. McDonald could define the precise problem. Tr. 161-63 (Dr. Leist), tr. 207 (Dr. McDonald stating "I don't know the actual cause in this case.").

The Veglias' motion is DENIED. The Veglias maintain that respondent has not presented evidence of a factor unrelated in accord with the dictates of 42 U.S.C. § 300aa–13(a)(2)(A). However, because the Veglias have not met their burden of proving the three factors listed in Althen, the Veglias are not entitled to compensation on a theory based on the hepatitis B vaccine. As the analysis in section III.B. implicitly shows, whether Domenick suffers a genetic defect or metabolic problem was not considered in determining whether the Veglias met their burden of proof.

V. Omnibus Autism Proceeding

Before the Veglias obtained Dr. Steinman's report, they indicated that if the special master found that they were not entitled to compensation, they wanted to the case to be transferred to the Omnibus Autism Proceeding. Pet'r Status Rep't, dated June 9, 2006. Given the present ruling, resolving this issue is appropriate. The Veglias may file a motion to transfer this case to the Omnibus Autism Proceeding. Any motion should explain, with citations to the medical records, why Domenick qualifies as someone with "autism spectrum disorder." Autism General Order #1.

The deadline for the Veglias to file this motion is Friday, March 13, 2009. The failure of the Veglias to file such a motion will constitute a waiver and will lead to a decision based upon this ruling.

VI. Conclusion

The Veglias have not established that they are entitled to compensation based upon the information presented. The Veglias may file a motion to transfer this case to the omnibus autism proceeding. The deadline for such a motion is Friday, March 13, 2009.

IT IS SO ORDERED.

S/ Christian J. Moran
Christian J. Moran
Special Master